Finding of No Significant Impact (FONSI)

Removal of Essential–Use Designation

Albuterol Used in Oral Pressurized Metered Dose Inhalers (MDIs)

CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

February 24, 2005

2003P.0029 FONS 2

FINDING OF NO SIGNIFICANT IMPACT

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions. Under the Clean Air Act (CAA), the Food and Drug Administration (FDA), in consultation with the Environmental Protection Agency (EPA), is required to determine whether an FDA-regulated product that contains an ozone depleting substance (ODS), such as chlorofluorocarbons (CFCs), is essential. Furthermore, Section 612 of the CAA requires EPA to establish a program to identify alternatives to Class I and II ODSs and to publish a list of acceptable and unacceptable substitutes (Significant New Alternatives Policy (SNAP)). The regulations at 21 CFR 2.125, *Use of Ozone-Depleting Substances; Essential-Use Determinations*, provides standards that FDA uses to determine which FDA-regulated products that contain an ODS are essential under the CAA. The attached environmental assessment (EA) constitutes the agency's environmental review for removal of the essential-use designation for albuterol MDIs under 21 CFR 2.125(g)(4). If the essential-use designation is removed, albuterol MDIs containing an ODS could not be marketed in the U.S. after a suitable transition period.

From an environmental perspective, removal of the essential-use designation for albuterol MDIs is clearly preferred. This action would eliminate the use of CFC propellants in albuterol MDI products while providing a continued supply of the drug product that uses a propellant (HFA-134a) that has been determined by EPA under its SNAP program to be an acceptable substitute for certain ODSs, including CFC-11. HFA-134a has zero ozone depletion potential but is a greenhouse gas. Removal of the essential-use designation for albuterol MDIs is consistent with the U.S. policy of limiting the production and use of ozone depleting substances (ODSs), including chlorofluorocarbons (CFCs), and would benefit the environment by reducing the use of ozone depleting CFC propellants.

The FDA, Center for Drug Evaluation and Research has carefully considered the potential environmental impact of removing the essential-use designation for the identified product and has concluded that this action will not, individually or cumulatively, have a significant adverse effect on the quality of the human environment and therefore an environmental impact statement is not required.

PREPARED BY
Florian Zielinski, Environmental Officer
Center for Drug Evaluation and Research

Florian Zielinski
2/24/2005

CONCURRED BY
Jon E Clark, Associate Director for Policy
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Jon E Clark
2/24/2005

Attachment: Environmental Assessment